Things To Consider Before Your Silicone Implant Surgery

State of California
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INTRODUCTION

Cosmetic or "plastic" surgery that places (implants) various types of silicone plastic into the human body has become very popular over the past two decades. In the early 1990s, the public became concerned over widespread press reports that silicone may cause harmful side effects, chronic disease, and possibly even fatal complications.

The California Legislature responded to this concern by passing the Cosmetic Implant Act of 1992. This law requires doctors to give written information to patients considering silicone implant surgery. The written information may be the manufacturer's patient

package insert or this summary prepared by the California Department of Health Services and published and distributed by the Medical Board of California.

This summary will help you better understand the risks of silicone implants. The State of California does not endorse any particular procedure nor does this brochure claim to provide an exhaustive analysis of all the potential benefits or risks associated with any particular procedure. Individuals must evaluate these for themselves with the help of their doctors.

You will gain the most from this brochure by reading it thoroughly and then discussing any questions you may have with your doctor before making your decision for silicone implant surgery.

What is silicone?

Silicone is a chemical made from the naturally occurring elements silicon, oxygen and hydrogen. Silicon is one of the most common elements on earth. It is usually found in quartz rock or ordinary white sand. Silicon found in quartz rock and white sand is called silicon dioxide because it is combined with oxygen from the air. Silicone is manufactured by chemically combining silicon dioxide from white sand, carbon from carbon dioxide, and the gases hydrogen and oxygen. After many steps silicone fluid is produced.

Silicone fluid is clear and is similar

to olive oil in thickness. Silicone fluid is widely used as a lubricant in medical and food preparation equipment. Silicone fluid can be made into silicone rubber or thickened into silicone gel. Many additional processing and testing steps are performed before silicone can be used for medical purposes. These include steps to assure purity, and testing to help assure that the material will not harm living tissue that it touches. This is known as biocompatability. Silicone rubber produced for medical purposes is molded into many forms including blocks, tubes or sheets used to make silicone implants. Silicone gel produced for medical purposes is used to fill hollow silicone implants to give the feel of soft body parts. It is also used directly in some eye surgeries.

What are the Medical Uses of Silicone?

There are many medical uses of silicone gel and silicone rubber. The first silicone implant was a small tube used to drain excess fluid surrounding the brain into the blood stream. Over 500,000 of these tubes have been used since 1955.

More recently, medical grade silicones have been used for bone implants, coatings for heart pacemakers, drain tubes for surgical wounds, tubes used to enter the blood stream or urinary tract, replacement lenses within the eye, and many other medical applications.

Two surgeons first used silicone rubber for plastic surgery for cosmetic purposes in 1961. In 1962, the first silicone rubber breast implant was commercially developed. Since that time, silicone rubber implants, some with a silicone gel filling, have also been developed for the calf muscles, chest muscles, facial bones, penis, testicle, nose and ear.

Silicone implants may be used for cosmetic purposes or for reconstruction after injury or illness (such as breast or testicular cancer). Silicone breast implant surgery has been the most frequently performed silicone implant surgery. The federal Food and Drug Administration (FDA) estimates that approximately 2 million American women now have breast implants.

What Is Being Done to Evaluate the Safety of Silicone Implants?

In 1976 Congress passed the first law requiring FDA to regulate the manufacture and marketing approval of medical devices, including silicone implants. A major protection provided by this law was that certain devices would require FDA's premarket approval before they could be sold. That is, manufacturers would have to provide FDA scientific evidence of safety and effectiveness before FDA would approve them for marketing.

Devices such as the silicone rubber and gel cosmetic implants were included in this premarket approval category but were allowed to stay on the market as "grandfathered" devices since they had been in commercial distribution before the law was passed. The new law said that the manufacturers of these devices would eventually have to provide FDA with scientific data to show that the devices are safe and effective.

Many research studies have been done since the early 1950's to determine the safety of silicone for medical uses. These included studying the effects of silicone materials implanted into animals, and laboratory tests specifically designed to evaluate the safety of materials intended to contact human tissues. These studies were able to identify very few negative effects associated with silicone as a surgical implant material. Silicone implant surgeries were performed routinely.

As silicone implant usage increased so did the number of adverse reaction reports. Between 1985 and September 17, 1996 FDA received 103,343 adverse reaction reports associated with silicone breast implants with silicone gel filler, and another 23,454 associated with silicone breast implants with saline (salt water) filler. FDA does not know what the actual rate of adverse reaction reports is (i.e., the percentage of implant recipients who have reported adverse reactions) because it does not have the authority to require manufacturers to provide them information about the actual number of patients who have received implants.

Nevertheless, there was concern that these may be more than should be expected. FDA took several actions in

response to these reports. In April 1991 FDA asked manufacturers of silicone gel-filled breast implants to submit scientific data showing safety and effectiveness. The data submitted was not enough for FDA to conclude that the devices were safe and effective. So, in April 1992, FDA removed silicone gel-filled breast implants from the market except for:

- use in controlled clinical studies for reconstruction after mastectomy,
- correction of congenital deformities,
- or replacement of ruptured silicone gel-filled implants for augmentation.

The purpose of the studies is to gather additional scientific data to evaluate the safety and effectiveness of gel-filled implants for these purposes. Data from completed studies may then be used to support an application to FDA for permission to resume general marketing of gel-filled implants for these purposes.

In order to conduct the studies, manufacturers of gel-filled implants must ask FDA for an investigational device exemption (IDE). FDA will not consider IDE applications for breast augmentation. Patients who choose to receive silicone gel-filled implants as part of these scientific studies must be advised of all known and possible risks and sign a consent form to participate in the study. Study participants will be closely monitored for adverse reactions.

FDA also is requiring manufacturers of saline-filled implants to submit scientific data to prove the safety and effectiveness of these implants. FDA has not yet set a deadline for submission of this data. In the interim, FDA is allowing saline-filled implants to remain on the market for use in both cosmetic and reconstructive surgery. This is because FDA considers saline-filled implants less risky.

Although they have the same silicone rubber envelope as gel-filled implants, leakage or rupture would release only salt water, not silicone gel, into the body. Manufacturers of saline-filled implants must provide written information on the known and possible risks of their products and implant recipients must sign a consent form.

Concerns about implant safety have caused health researchers to conduct studies as well. Some studies involve the review of large numbers of medical records to see if persons with implants experience an abnormally high level of health problems compared to persons without implants.

Two recent studies, the Harvard Nurses' Health Study and a Mayo Clinic study compared the rates of immune-related diseases in women with saline and gel-filled implants to those without implants. These and other similar studies were not able to identify an increased risk of these types of diseases for implant recipients. A limitation of these types of studies is that they are not able to detect very small increases in risk

A different type of study involves asking people questions about their

health. One such study reported a slightly increased risk of connective tissue disease in women with breast implants. Hennekens and co-workers at Harvard University evaluated the responses of almost 400,000 (nearly 11,000 with gel-filled or saline implants) women to a questionnaire. They found that over a 10-year period women with breast implants were 1.24 times more likely to report having some type of connective tissue disease than women without breast implants.

This applies to all of the connective tissue diseases considered together. When calculated individually, the increased risk of each of these diseases was not statistically significant. This study was limited in its design because self-reported disease was not confirmed by medical records, the study cannot differentiate between the risk of saline and gel-filled implants, and not all women asked to participate completed the questionnaire. For these and other reasons, the actual risk may be different than that reported by the study.

RISKS ASSOCIATED WITH SILICONE BREAST IMPLANTS

Many women have had silicone breast implant surgery with few or no problems. But some women who have had silicone breast implant surgery have had problems. Anyone considering silicone breast implant surgery should know that there is a risk that they may have problems too. FDA describes the risks of silicone breast implant surgery as being either "known" or "possible."

Known risks are those that, when they occur, can be attributed to the surgery or the implant itself. **Possible risks** are problems that women have had, but that cannot necessarily be attributed to the implants. This is because, after looking at all available scientific information, FDA scientists found that women with implants do not have a significantly higher rate of these problems than women without implants.

But scientific studies are not always able to detect small but important increases in risk. So silicone breast implants cannot be ruled out as a possible risk factor for these types of problems. This is why FDA describes them as possible risks, and requires that potential implant recipients be informed of these possible, although unlikely, risks.

KNOWN *RISKS OF SILICONE BREAST IMPLANTS*

Surgical Risks

- ✓ Possible complications of general anesthesia, including nausea, vomiting and possible inhalation of stomach contents, pneumonia, fever, brain damage and death.
- ✓ Infection
- ✓ Hematoma — Hematoma is the collection of blood that may cause swelling, pain and bruising, perhaps requiring surgery to drain the blood.
- ✓ Hemorrhage — Hemorrhage is abnormal bleeding.
- ✓ Thrombosis — Thrombosis is abnormal clotting.
- ✓ Skin necrosis — This is skin tissue death resulting from insufficient blood flow to the skin. The chance of skin necrosis may be increased by radiation treatments, cortisone-like drugs, an implant too large for the available space (pocket under the skin made by the surgeon for placement of the implant) or smoking.

Implant Risks

- ✓ Capsular contracture — This is a hardening of the breast due to shrinkage of the scar tissue that naturally forms around the implant.
- ✓ Leak or rupture — Silicone gel-filled implants may leak or rupture, slowly releasing silicone gel into the surrounding tissue; saline-filled implants may rupture suddenly and deflate.

- ✓ Temporary or permanent change or loss of sensation in the nipple or breast tissue.
- ✓ Formation of calcium deposits in surrounding tissue, possibly causing pain and hardening.
- ✓ Shifting from the original placement, giving the breast an unnatural look.
- ✓ Interference with mammography readings, possibly delaying breast cancer detection by 'hiding' a suspicious area. Also, it may be difficult to distinguish calcium deposits formed in the scar tissue from a tumor when interpreting the mammogram.
- ✓ When making an appointment for a mammogram, the woman should tell the scheduler she has implants to make sure qualified personnel are onsite. At the time of the mammogram she also should remind the technician she has implants before the procedure is done, so the technician can use special techniques to obtain the best mammogram and to avoid rupturing the implant.

POSSIBLE *RISKS OF SILICONE BREAST IMPLANTS*

- ✓ Autoimmune-like disorders — Signs of these types of disorders include joint pain and swelling; skin tightness, redness or swelling; swelling of hands and feet; rash; swollen glands or lymph nodes; unusual fatigue; general aching.
- ✓ Greater chance of getting colds, viruses and flu; unusual hair loss; memory problems; headaches; muscle weak-

ness or burning; nausea or vomiting; and irritable bowel syndrome.

- ✓ Fibrositis/fibromyalgia-like disorders — These disorders result in pain, tenderness and stiffness of muscles, tendons and ligaments.
- ✓ Cancer — There is no scientific evidence that silicone breast implants can increase the risk of cancer, but scientists cannot completely rule out the possibility. Average follow-up time of completed studies in women has been too short to fully evaluate this risk.
- ✓ Breast Feeding — It is not known if the small amounts of silicon that "bleed" from gel-filled and saline-filled implants can get into breast milk, and, if so, whether it could affect the nursing infant. More study is needed.
- ✓ Pregnancy — It is not known if a mother's breast implants can have an effect on the fetus.

OTHER SILICONE IMPLANT RISKS

Many of the known risks described above for silicone breast implants apply to any procedure that places a silicone implant in the human body

The surgical risks noted above can result from any implant surgery and will vary depending on the general health of the patient, skill of the surgeon, size and scope of the implant and numerous other factors.

The implant risks described for silicone breast implants apply to silicone implants generally. Implants in areas other than the breast would not, of course, interfere with mammography, but could interfere with other diagnostic x-rays or imaging.

Two risk categories mentioned as possible risks of silicone breast implants (autoimmune-like disorders and fibrositis/fibromyalgia-like disorders) are rare in the general population as well as in silicone breast implant recipients. While it is logical to ask if these possible risks might apply to other silicone implants, more information is needed before this can be answered.

Risks described by manufacturers in the labeling for silicone implants other than breast implants include:

- ✓ Displacement or shifting of the implant. This can occur if the surgical pocket is too large for the implant.
- ✓ Inadequate tissue covering. A surgical pocket that is too small, or an implant that is too large can result in skin thinning or loss and result in the implant protruding from the implant site. This may require surgical removal of the implant.
- ✓ Visibility of silicone implant. This is most frequently reported with nasal implants and happens when the person stands next to a strong light or in direct sunlight and the implant becomes clearly outlined.

Risks of Silicone Penile Implants

- ✓ Failure of the implant to function as intended
- ✓ Sizing errors
- ✓ Infection, and loss of penile tissue.
- ✓ Loss of any natural ability to make the penis erect
- ✓ Loss of penile sensation or sensitivity
- ✓ Movement or wear of the penile implant
- ✓ Urinary obstruction or other complications related to implant movement.

WHERE CAN I GET MORE INFORMATION?

The best source of information about your implant surgery is your doctor. He or she knows your health status, and can best inform you of those risks you need to consider.

Call the FDA consumer information line at 1-888-INFOFDA OR 1-888-463-6332. Consumers can call this number for information about any product that the FDA regulates, including silicone implants. For the latest information about silicone breast implants, ask for a copy of the FDA breast implant information package. This information package also is available from the FDA Internet site at www.fda.gov (from the FDA main page click on the "Index" icon, then choose the breast implant link).

Some silicone implant manufacturers provide patient information brochures that answer commonly asked questions about their implants. Ask your doctor if one is available for the implant you are considering and, if so, get a copy and read it. If not, ask your doctor for a copy of the package insert for the silicone implant you are considering.

Package inserts provide doctors important information about possible risks. The package insert is written in technical language and your doctor may have to help you understand it.

State of California
Department of Health Services
714/744 P Street
P.O.Box 942732
Sacramento, CA 94234–7320

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Silicone Implant Brochure
Medical Board of California
1426 Howe Avenue, Suite 54
Sacramento, CA 95825-3236

or FAX to 916 • 263 • 2479

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Medical Device Safety Section
Food and Drug Branch
Division of Food, Drug and Radiation Safety
California Department of Health Services
601 North 7th Street, MS 357
P.O. Box 942732
Sacramento, CA 94234-7320

Phone: 916 • 445• 2263